

JG07 Rec'd PCT/PTO 07 MAR 2002

FORM PTO-1390  
(REV. 11-2000)

U S DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

ATTORNEY'S DOCKET NUMBER  
31446-179039

**TRANSMITTAL LETTER TO THE UNITED STATES  
DESIGNATED/ELECTED OFFICE (DO/EO/US)  
CONCERNING A FILING UNDER 35 U.S.C. 371**

U.S. APPLICATION NO. (If known, see 37 CFR 1.5)  
Unassigned **10/070540**

INTERNATIONAL APPLICATION NO.  
PCT/IN99/00042

INTERNATIONAL FILING DATE  
September 7, 1999

PRIORITY DATE CLAIMED  
September 7, 1999

TITLE OF INVENTION: **A PHARMACEUTICAL AYURVEDIC PREPARATION**

APPLICANT(S) FOR DO/EO/US: **Vaidya Balendu PRAKASH**

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☒ This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2. ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
3. ☐ This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below.
4. ☐ The US has been elected by the expiration of 19 months from the priority date (Article 31).
5. ☒ A copy of the International Application No. PCT/IN99/00042 published as WO 01/17540 A1.
  - a. ☒ is attached hereto (required only if not communicated by the International Bureau).
  - b. ☐ has been communicated by the International Bureau. (attach form IB 308)
  - c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☐ An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).
  - a. ☐ is attached hereto.
  - b. ☐ has been previously submitted under 35 U.S.C. 154(d)(4)
7. ☐ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3)).
  - a. ☐ are attached hereto (required only if not communicated by the International Bureau).
  - b. ☐ have been communicated by the International Bureau.
  - c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
  - d. ☐ have not been made and will not be made.
8. ☐ An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
9. ☐ An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).
10. ☐ An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

**Items 11 to 20 below concern document(s) or information included:**

11. ☐ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
12. ☐ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
13. ☒ A **FIRST** preliminary amendment.
14. ☐ A **SECOND** or **SUBSEQUENT** preliminary amendment.
15. ☐ A substitute specification.
16. ☐ A change of power of attorney and/or address letter.
17. ☐ A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 35 U.S.C. 1.821 - 1.825.
18. ☐ A second copy of the published international application under 35 U.S.C. 154(d)(4).
19. ☐ A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).
20. ☐ Other items or information:
- 20a. ☐ For purposes of examination, please insert the annexes to the IPER, so that the application will comprise the following pages of the English translation:  
 Specification: **Original pages**  
 Claims: **Amended claims -**

U.S. APPLICATION NO. (if known) <b>10/070540</b>		INTERNATIONAL APPLICATION NO.		ATTORNEY'S DOCKET NUMBER	
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<p>21. <input checked="" type="checkbox"/> The following fees are submitted:</p> <p><b>BASIC NATIONAL FEE (37 CFR 1.492 (a) (1) - (5):</b></p> <p>Neither international preliminary examination fee (37 CFR 1.482) nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO and International Search Report not prepared by the EPO or JPO..... \$1040.00</p> <p>International preliminary examination fee (37 CFR 1.482) not paid to USPTO but International Search Report prepared by the EPO or JPO..... \$890.00</p> <p>International preliminary examination fee (37 CFR 1.482) not paid to USPTO but international search fee (37 CFR 1.445(a)(2)) paid to USPTO ..... \$710.00</p> <p>International preliminary examination fee (37 CFR 1.482) paid to USPTO but all claims did not satisfy provisions of PCT Article 33(1)-(4) ..... \$690.00</p> <p>International preliminary examination fee (37 CFR 1.482) paid to USPTO and all claims satisfied provisions of PCT Article 33(1)-(4) ..... \$100.00</p> <p style="text-align: right;"><b>ENTER APPROPRIATE BASIC FEE AMOUNT =</b></p> <p>Surcharge of \$130.00 for furnishing the oath or declaration later than <input type="checkbox"/> 20 <input type="checkbox"/> 30 months from the earliest claimed priority date (37 CFR 1.492(e)).</p> <table border="1" style="width:100%; border-collapse: collapse;"> <thead> <tr> <th style="width:20%;">CLAIMS</th> <th style="width:20%;">NUMBER FILED</th> <th style="width:20%;">NUMBER EXTRA</th> <th style="width:20%;">RATE</th> <th style="width:20%;">\$</th> </tr> </thead> <tbody> <tr> <td>Total claims</td> <td>18 - 20 =</td> <td>0</td> <td>x \$18.00</td> <td>\$ 0</td> </tr> <tr> <td>Independent claims</td> <td>2 - 3 =</td> <td>0</td> <td>x \$80.00</td> <td>\$ 0</td> </tr> <tr> <td colspan="3">MULTIPLE DEPENDENT CLAIMS(S) (if applicable)</td> <td>+ \$270.00</td> <td>\$ 0</td> </tr> <tr> <td colspan="4" style="text-align: right;"><b>TOTAL OF ABOVE CALCULATIONS =</b></td> <td>\$1,040.00</td> </tr> <tr> <td colspan="4"> <input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. The fees indicated above are reduced by 1/2.         </td> <td style="text-align: center;">+</td> </tr> <tr> <td colspan="4" style="text-align: right;"><b>SUBTOTAL =</b></td> <td>\$1,040.00</td> </tr> <tr> <td colspan="4">Processing fee of \$130.00 for furnishing the English translation later than <input type="checkbox"/> 20 <input type="checkbox"/> 30 months from the earliest claimed priority date (37 CFR 1.492(f)).</td> <td style="text-align: center;">+</td> </tr> <tr> <td colspan="4" style="text-align: right;"><b>TOTAL NATIONAL FEE =</b></td> <td>\$1,040.00</td> </tr> <tr> <td colspan="4">Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property</td> <td style="text-align: center;">+</td> </tr> <tr> <td colspan="4" style="text-align: right;"><b>TOTAL FEES ENCLOSED =</b></td> <td>\$1,040.00</td> </tr> <tr> <td colspan="4"></td> <td style="text-align: right;"><b>Amount to be refunded:</b></td> <td style="text-align: center;">\$</td> </tr> <tr> <td colspan="4"></td> <td style="text-align: right;"><b>charged:</b></td> <td style="text-align: center;">\$</td> </tr> </tbody> </table>				CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE	\$	Total claims	18 - 20 =	0	x \$18.00	\$ 0	Independent claims	2 - 3 =	0	x \$80.00	\$ 0	MULTIPLE DEPENDENT CLAIMS(S) (if applicable)			+ \$270.00	\$ 0	<b>TOTAL OF ABOVE CALCULATIONS =</b>				\$1,040.00	<input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. The fees indicated above are reduced by 1/2.				+	<b>SUBTOTAL =</b>				\$1,040.00	Processing fee of \$130.00 for furnishing the English translation later than <input type="checkbox"/> 20 <input type="checkbox"/> 30 months from the earliest claimed priority date (37 CFR 1.492(f)).				+	<b>TOTAL NATIONAL FEE =</b>				\$1,040.00	Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property				+	<b>TOTAL FEES ENCLOSED =</b>				\$1,040.00					<b>Amount to be refunded:</b>	\$					<b>charged:</b>	\$	<p><b>CALCULATIONS PTO USE ONLY</b></p>	
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a. ☒ A check in the amount of \$ 1,040.00 to cover the above fees is enclosed.

b. ☐ Please charge my Deposit Account No. \_\_\_\_\_ in the amount of \$ \_\_\_\_\_ to cover the above fees.

c. ☒ The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 22-0261. A duplicate copy of this sheet is enclosed.

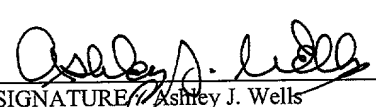
d. ☐ Fees are to be charged to a credit card. **WARNING:** Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

**NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137 (a) or (b)) must be filed and granted to restore the application to pending status.**

SEND ALL CORRESPONDENCE TO:

**VENABLE**  
 P.O. Box 34385  
 Washington D.C. 20043-9998  
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 SIGNATURE Ashley J. Wells

REGISTRATION NUMBER: 29,847

March 7, 2002  
 DATE

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:  
Vaidya Balendu PRAKASH

Int'l Appl. No.: PCT/IN99/00042

Int'l Filing Date: September 7, 1999

For: A PHARMACEUTICAL  
AYURVEDIC PREPARATION

Art Unit: NOT YET ASSIGNED

Examiner: NOT YET ASSIGNED

Atty. Docket No.: 31446-179039

Customer No.



26694

PATENT TRADEMARK OFFICE

**PRELIMINARY AMENDMENT**

Assistant Commissioner for Patents  
Washington, D.C. 20231

Prior to calculation of any fees, please amend the Application to eliminate multiple claim dependency and for formal reasons as follows.

**IN THE CLAIMS:**

Please replace claims 1, 9 and 15 with new claims 1, 9, and 15 which have been amended as shown in the attached marked-up copy.

1. (Once amended) A process for preparing an ayurvedic preparation, comprising the steps of:

subjecting silver, mercury, sulphur and arsenic trisulphide to the steps of detoxification, grinding the detoxified mercury and silver in the presence of a citrus juice and then adding detoxified sulphur and again subjecting to the steps of grinding to obtain a greyish black

powder, adding adding detoxified arsenic trisulfide thereto and subjecting to the step of grinding, imparting a shape such as a ball thereto, coating the ball with detoxified sulphur in the presence of a citrus juice and subjecting the coated ball to the step of slow firing, adding detoxified arsenic trisulphide and firing, repeating said steps of addition and firing ground in a citrus juice such that the weight of the ball is reduced by at least 10% to obtain an intermediate, adding serpentine and delphenium root thereto.

9. (Once amended) The process as claimed in claim 3, wherein said repetitive steps comprise 7 repetitive steps.

15. (Once amended) The process as claimed in claim 14, wherein one part of detoxified sulphur is ground in citrus juice and coated to said shape and then introduced in said vessel and fired in cowdung.

#### REMARKS

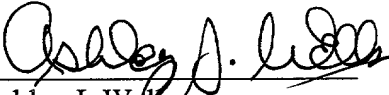
This Preliminary Amendment replaces claims 1, 9 and 15 with new claims 1, 9, and 15 which have been amended as shown in the attached marked-up copy of these claims.

**Claims 1-18 are pending in this U.S. National Stage Application.**

An early action on the merits is earnestly requested.

Respectfully submitted,

Date: March 7, 2002

  
Ashley J. Wells  
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DC2-DOCS1-356694

20070540-052402  
2004250-04502007

## **MARKED-UP VERSION OF CLAIMS 1, 9 and 15:**

1. (Once amended) A process [on] for preparing an ayurvedic preparation, comprising [in] the steps of:

subjecting silver, mercury, sulphur and arsenic trisulphide to the steps of detoxification, grinding the detoxified mercury and silver in the presence of a citrus juice and then adding detoxified sulphur and again subjecting to the steps of grinding to obtain a greyish black powder, adding adding detoxified arsenic trisulfide thereto and subjecting to the step of grinding, imparting a shape such as a ball thereto, coating the ball with detoxified sulphur in the presence of a citrus juice and subjecting the coated ball to the step of slow firing, adding detoxified arsenic trisulphide and firing, repeating said steps of addition and firing ground in a citrus juice such that the weight of the ball is reduced by at least 10% to obtain an intermediate, adding serpentine and delphenium root thereto.

9. (Once amended) [A] The process as claimed in [claims 3 to 7] claim 3, wherein said repetitive steps comprise 7 repetitive steps.

15. (Once amended) [A] The process as claimed in claim 14, wherein one part of detoxified sulphur is ground in citrus juice and coated to said shape and then introduced in said vessel and [tired] fired in cowdung.

WO 01/17540

TITLE OF THE INVENTIONA PHARMACEUTICAL AYURVEDIC PREPARATIONFIELD OF INVENTION

This invention relates to a pharmaceutical ayurvedic preparation for the treatment of leukemia. The preparation of the present invention has a particular application for the treatment of acute myeloid leukemia, acute promyelocytic leukemia and acute lymphoblastic leukemia. The present invention also relates to a process for preparing the pharmaceutical ayurvedic preparation.

PRIOR ART

Chemical pharmaceutical preparations are normally prescribed for treatment of leukemia. No prior public literature is known for an ayurvedic preparation for treatment of leukemia.

OBJECTS OF THE INVENTION

An object of this invention is to propose a novel ayurvedic preparation for treatment of leukemia.

Another object of this invention is to propose an ayurvedic preparation for treatment of leukemia and which does not have any side effects.

DESCRIPTION OF THE INVENTION

According to this invention, there is provided a process for the preparation of an ayurvedic preparation comprising in the steps of subjecting silver, mercury, sulphur and arsenic trisulphide to the steps of detoxification, grinding the detoxified mercury and silver in the presence of a citrus juice and then adding detoxified sulphur and again subjecting to the step of grinding to obtain a greyish black powder, adding detoxified arsenic trisulphide thereto and subjecting to the step of grinding,

imparting a shape such as a ball thereto, coating the ball with detoxified sulphur in the presence of a citrus juice and subjecting the coated ball to the step of slow firing, adding detoxified arsenic trisulphide and firing, repeating said steps of addition and firing ground in a citrus juice such that the weight of the ball is reduced by at least 10% to obtain an intermediate, adding serpentine and delphenium root thereto.

The expression detoxification used herein is not intended to imply that silver, mercury, sulphur and arsenic trisulphide are treated such as to detoxify the elements in the mixture stage, but to imply that such elements do not exhibit any adverse side effects in the end preparations.

In accordance with this invention, silver in a purified form which is subjected to a step of detoxification. Such a step of detoxification consists in converting silver bars into sheets and then to repetitive steps of heating and introduction into sesame oil. By way of example and without implying any limitation, such a step of heating and introducing into sesame oil is repeated several times, such as seven times.

Thereafter, the treated silver is again heated and then introduced into butter milk. The step of heating and introduction into butter milk after each step of heating is also repeated several times, such as seven times.

The partially detoxified silver is again heated and then introduced into cow urine and which step is repeated several times, such as seven times.

The treated silver is again heated and introduced into a herbal composition. Such a step of heating and introduction into a herbal composition is again preferably repeated several times, such as seven times. The herbal composition comprises amla, harar and behera and present preferably in equal parts.



The treated silver is again heated several times and then after each step of heating is treated with kutli. Such a step is also repeated several times, such as seven times. The aforesaid step consists in the detoxification of silver.

5 The process of the present invention includes the step of detoxification of mercury. For this purpose, an amalgam is first prepared from a mixture of copper, which may be in the form of wire, in lemon juice and mercury. Preferably  $1/2-1/8$  parts of copper wire is added to every  
10 one part of mercury which is then ground to obtain an amalgam. Such an amalgam is then subjected to a step of distillation to extract mercury therefrom. The step of grinding and distillation is effected several times in order to obtain detoxified mercury. Preferably but without  
15 implying any limitation to the step of detoxification is carried seven times.

The next step is the process consists in the purification of sulphur. For this purpose, crystalline sulphur is introduced into a crucible and having melted butter  
20 therein. Preferably, equal amounts of melted butter and sulphur are introduced into the crucible and heated on a low fire. Trifla is then added to the mixture and whereby a scum of pure sulphur is formed and removed.

The process also comprises in introducing arsenic trisulphide disposed within a cotton cloth and introduced  
25 into a vessel containing calcium oxide solution and then into another vessel of pumpkin juice or vice versa. The arsenic trisulphide is heated in calcium oxide solution and pumpkin juice for a period of 3 to 5 hours, such as  
30 4 hours and, then dried.

The next step in the process consists in grinding detoxicated silver and mercury in the presence of citrus juice, such as lemon juice, and such that detoxicated silver is dissolved in mercury. Preferably, one part of  
35 detoxicated silver is added to one part of mercury and

ground in the presence of lemon juice to form a powder. Thereafter, purified sulphur is added thereto and ground to greyish black powder. Preferably, one part of purified sulphur is added thereto. Upon grinding and obtaining a greyish black powder purified arsenic trisulphide is added to the greyish black powder in the presence of a citrus juice, such as lemon juice, which is then subjected to a step of grinding to obtain a paste. Such a paste is shaped into balls and then air dried. Preferably, one part of arsenic disulphide is added thereto.

The next step in the process consists in coating such balls with a paste of sulphur in lemon juice.

Such a ball is introduced into an earthenware vessel which is sealed with a strip of cotton and dipped in clay. The vessel is introduced into a bed containing dry cowdung which is then fired such that the temperature rises to a temperature of 500-600°C and then gradually reduces.

The vessel is then opened and arsenic trisulphide is added thereto in the presence of lemon juice and subjected to the step of firing. The step of adding arsenic trisulphide and firing is repeated 30-60 time to obtain a more potent intermediate product, and such that the weight is reduced by at least 10%.

Such an intermediate product is thereafter added to serpentine and delphenium root and ground in distilled rose water for approximately seven days repeated with sandalwood water for seven day and finally with latakasturi water for seven days to obtain a paste which is then shaped into balls.

Further objects and advantages of this invention will be more apparent from the ensuing example and clinical trials.

#### EXMAPLE

Silver, mercury, sulphur and arsenic trisulphide was

detoxified in a manner as described hereinabove.  
Thereafter, the ball was prepared consisting of:

detoxified silver = 250 gms

detoxified mercury = 250 gms

detoxified sulphur = 500 gms

detoxified arsenic

trifulphide= 250 gms

The ball had a weight of 1250 gms and then provided with a coating of detoxified sulphur ground in lemon juice and such that the coated ball had a weight of 1400 gms. Such a ball was then introduced into an earthen vessel or pot and sealed with a strip of cotton, dipped in clay. The vessel is introduced into a pit containing cow dung and fired. Such a process was repeated as shown in Table 1 to produce the intermediate product. Thereafter, the final product was prepared in a manner as described herein above.

T A B L E 1

VESSEL	GROUND WITH ARSENIC	LEMON Juice	PERIOD DAYS	WT.BEFORE FIRING gm	PERIOD OF FIRING days	WT. AFTER FIRING gm
1	0	0	0	1400	1	940
1	25g	450ml	6	1120	1	975
1	25g	400ml	17	1100	1	940
1	25g	400ml	22	1050	1	940
2	25g	400ml	29	1110	1	930
2	25g	450ml	36	1090	1	975
2	25g	400ml	41	1070	1	940
2	25g	400ml	50	1040	1	940
2	25g	450ml	58	1050	1	930
2	25g	550ml	67	1080	1	940

	2	25g	500ml	73	1070	1	950
	2	25g	750ml	80	1070	1	970
	2	25g	750ml	84	1050	1	970
	2	25g	800ml	89	1060	1	940
5	2	25g	900ml	96	1080	1	950
	2	25g	900ml	103	1100	1	1000
	2	25g	900ml	110	1120	1	970
	2	25g	900ml	116	1050	1	950
	2	25g	900ml	121	1020	1	950
10	2	25g	750ml	128	1050	1	990
	2	25g	800ml	135	1080	1	980
	2	25g	750ml	140	1050	1	950
	2	25g	650ml	148	1050	1	950
	2	25g	700ml	153	1020	1	950
5	2	25g	700ml	159	1080	1	980
	2	25g	650ml	173	980	1	920

The results of clinical trials on patients with the preparation of the present invention were as follows:

T A B L E 2

DETAILS OF THE PATIENTS WHO COMPLETED  
90 DAYS OF TREATMENT FOR ACUTE  
PROMYELOCYTIC LEUKEMIA WITH PRESENT  
MEDICINE

S.No.	Name/Age	Category	<u>Duration of Treatment</u>		Status after
		<u>Fresh/</u> Relapse	From	To	90 days
<hr/>					
1.	ARK/41	F	09.09.1997	30.01.1998	Complete remission on 26.12.1997
2.	VR/40	F	04.12.1997	22.04.1999	Complete remission on 14.03.1998
3.	PK/50	F	04.12.1997	20.03.1998	Complete remission

					on 16.03.1998
4.	VC/48	R	22.12.1997	15.04.1998	Complete remission on 01.04.1998
5.	F/29	R	09.04.1998	07.12.1998	Bone marrow not done, blood report normal
6.	NS/15	R	18.04.1998	30.01.1999	Complete remission on 25.07.1998
7.	PR/48	F	26.01.1999	15.05.1999	Complete remission on 12.04.1999
5 8.	MS/28	R	19.02.1999	15.06.1999	Complete remission on 11.06.1999
9.	PS/29	R	25.03.1999	05.07.1999	Complete remission on 03.07.1999
10.	MN/30	R	30.03.1999	10.07.1999	Complete remission on 05.07.1997

F-Fresh, R-Relapse

T A B L E 3

DETAILS OF BONE MARROW OF THE PATIENTS WHO  
COMPLETED 90 DAYS OF TREATMENT FOR ACUTE  
PROMYELOCYTIC LEUKEMIA

S.No.	Name/Age	Before Ayurvedic treatment	After 90 days of Ayurvedic treat- ment
1.	ARK/41	BM no.5239863, replaced with abnormal promyelocytes-M3	PS and BM no. 523986-D, is free of evidence of M3, normal hemopoietic cell
15 2.	VR/40	Bone marrow shows abnormal promyelocytes-M3	Bone marrow in remission, no

			promyelocytic cells seen
3.	PK/50	Bone marrow replaced with abnormal promyelocytes-M3	Bone marrow in remission with normal cells
4.	VC/48	Bone marrow shows hyper granulated M3 cells	Bone marrow in remission with normal hemopoitic cells
5.	F/29	Bone marrow shows abnormal promyelocytes-M3	Bone marrow not done
6.	NS/15	Bone marrow shows 60-65% abnormal promyleocytes,APML relapse, N <sub>8-10</sub> , L <sub>3-5</sub> , MRBC 25%	Bone marrow in remission, no APML cells identi- fied, PS shows P <sub>64</sub> L <sub>33</sub> E <sub>2</sub> M <sub>1</sub>
7.	PR/48	Bone marrow shows hyper granulated promyleocytes AML-M3	Bone marrow shows normal hemopoitic with mild megalo- blastic change. There is no morphological evidence of residual leukemia
8.	MS/28	Bone marrow in relapse- AML-M3	Bone marrow shows normal hemopoitic. No leukemic cells identified
9.	PS/29	Bone marrow shows total replacement by abnormal hyper granular promyleocytes	Bone marrow shows normal hemopoitic cells of all series. No evidence of leuk- emia seen
10.	MN/30	Bone marrow shows abnormal	Bone marrow shows

promyelocytes along with  
few normal neutrophils-  
AML-M3 relapse

normal hemopoietic  
cells in all  
series. No  
evidence of  
residual leukemia

T A B L E  
DETAILS OF BLOOD REPORT OF TREATED APML CASES

S. No.	Name/Age	Blood report	First day	After 30 days	After 60 days	After 90 days
1.	ARK/41	Hb gm%	7.1	9.9	13.5	14.8
		TLC	1100	1450	5100	3100
		DLC	N <sub>10</sub> L <sub>30</sub> Abn <sub>60</sub>	N <sub>31</sub> L <sub>69</sub>	N <sub>60</sub> L <sub>34</sub> E <sub>6</sub>	N <sub>57</sub> L <sub>27</sub> E <sub>10</sub> M <sub>4</sub>
		ESR	138	37	8	-
		Platelets	19000	258000	172000	174000
2.	VR/40	Hb gm %	5.6	8.2	9.6	10.0
		TLC	1600	620	3200	3900
		DLC	N <sub>35</sub> L <sub>29</sub> E <sub>2</sub> M <sub>2</sub> Abn <sub>30</sub>	N <sub>32</sub> L <sub>22</sub> E <sub>4</sub> M <sub>2</sub> Abn <sub>20</sub>	N <sub>40</sub> L <sub>38</sub> E <sub>4</sub> Abn <sub>18</sub>	N <sub>73</sub> L <sub>21</sub> E <sub>4</sub> M <sub>2</sub>
		ESR	-	-	-	-
		Platelets	40000	180000	200000	200000
3.	PK/50	Hb gm %	10.2	9.3	10.1	13.9
		TLC	2000	6800	7000	9000
		DLC	N <sub>7</sub> L <sub>10</sub> M <sub>2</sub> Abn <sub>81</sub>	N <sub>70</sub> L <sub>30</sub>	N <sub>66</sub> L <sub>33</sub> E <sub>1</sub>	N <sub>63</sub> L <sub>37</sub>
		ESR	-	-	10	-
		Platelets	35000	25000	252000	330000
4.	VC/48	Hb gm %	8.0	9.5	11.8	9.6
		TLC	28000	650	7500	4800
		DLC	N <sub>30</sub> L <sub>35</sub> E <sub>5</sub> M <sub>4</sub> Abn <sub>26</sub>	N <sub>20</sub> L <sub>80</sub>	N <sub>58</sub> L <sub>26</sub> M <sub>2</sub> Abn <sub>14</sub>	N <sub>79</sub> L <sub>13</sub> Abn <sub>4</sub>
		ESR	75	-	-	-
		Platelets	110000	22000	85000	120000
5.	F/29	Hb gm %	9.0	9.0	5.0	9.6

		TLC	4900	4900	2500	1000
		DLC	N <sub>8</sub> L <sub>47</sub> M <sub>5</sub> Abn <sub>40</sub>	N <sub>8</sub> L <sub>45</sub> M <sub>5</sub> Abn <sub>40</sub>	N <sub>45</sub> L <sub>54</sub> B <sub>1</sub>	N <sub>26</sub> L <sub>5</sub> E <sub>1</sub> Abn <sub>46</sub>
		ESR	-	-	90	130
		Platelets	75000	75000	18000	55000
6.	NS/15	Hb gm %	12.9	8.4	11.0	11.7
		TLC	400	63200	7900	8500
		DLC	N <sub>64</sub> L <sub>36</sub>	N <sub>5</sub> L <sub>10</sub> Abn <sub>85</sub>	N <sub>57</sub> L <sub>40</sub> E <sub>3</sub>	N <sub>60</sub> L <sub>37</sub> E <sub>3</sub>
		ESR	-	42	5	5
		Platelets	130000	64000	238000	218000
7.	PR/48	Hb gm %	12.7	10.2	10.5	11.4
		TLC	2000	3000	3500	5500
		DLC	N <sub>7</sub> L <sub>43</sub> Abn <sub>50</sub>	N <sub>13</sub> L <sub>27</sub> E <sub>4</sub> Abn <sub>56</sub>	N <sub>48</sub> L <sub>37</sub> E <sub>6</sub> Abn <sub>2</sub> B <sub>1</sub>	N <sub>55</sub> L <sub>41</sub> B <sub>1</sub> Abn <sub>2</sub>
		ESR	43	-	-	-
		Platelets	76000	90000	298000	310000
8.	MS/28	Hb gm %	7.0	10.5	13.0	14.3
		TLC	12200	5700	7200	9200
		DLC	N <sub>8</sub> L <sub>30</sub> Abn <sub>62</sub>	N <sub>55</sub> L <sub>44</sub> E <sub>1</sub> M <sub>2</sub>	N <sub>73</sub> L <sub>22</sub> E <sub>5</sub>	N <sub>64</sub> L <sub>33</sub> E <sub>3</sub>
		ESR	48	5	-	-
		Platelets	36000	103000	141000	169000
9.	PS/29	Hb gm %	8.4	12.2	15.0	14.9
		TLC	2240	2900	5200	4600
		DLC	N <sub>15</sub> L <sub>10</sub> M <sub>5</sub> Abn <sub>70</sub>	N <sub>33</sub> 4L <sub>50</sub> 5E <sub>24</sub> 4M <sub>13</sub> 4B <sub>0</sub> 3	N <sub>46</sub> 9L <sub>33</sub> 2E <sub>8</sub> 3M <sub>11</sub> 2B <sub>0</sub> 4	N <sub>48</sub> 7L <sub>30</sub> 5E <sub>8</sub> 6M <sub>12</sub> 1B <sub>01</sub> 7
		ESR	-	-	5	7
		Platelets	25000	298000	202000	189000
10.	MN/30	Hb gm %	6.5	9.0		9.8
		TLC	8200	7300		5600
		DLC	N <sub>27</sub> L <sub>48</sub> E <sub>1</sub> Abn <sub>24</sub>	N <sub>71</sub> L <sub>23</sub> M <sub>6</sub>		N <sub>82</sub> L <sub>17</sub> M <sub>1</sub>
		ESR	-	-		60
		Platelets	120000	230000		150000

N-Neutrophils, L-Lymphocyte, E-Eosinophils, M-Monocyte, B-Basophil,  
Abn-Abnormal cell

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DETAILS OF LIVER, KIDNEY FUNCTION AND LIPID PROFILE OF THE PATIENTS  
TREATED FOR ACUTE PROMYELOCYTIC LEUKEMIA

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S.no.	Name/Age	Pre Ayurvedic treatment			After 90 days of Ayurvedic treatment		
		LFT	Lipid profile	KFT	LFT	Lipid profile	KFT
1.	ARK/41	NA	NA	NA	Bilirubin (T)-1.2 mg/dl Bilirubin(D) -0.3 mg/dl Protein total -7.8 mg/dl SGOT-29, SGPT-35 Alk.P.-161	NA  NA  NA  NA	Blood -23 mgs/dl Serum-0.8 mg/dl creat-inine
2.	VR/40	NA	NA	NA	NA	NA	NA
3.	PK/50	Bilirubin(T)-0.4 mgs/100ml Bilirubin(C)-0.2 mgs/100ml SGOT-75u/l, SGPT-35 Alk.P.-324 u/l	NA	Blood urea NA -21mgs/100 Serum creatinine -1.1 mgs/100ml	NA	NA	Blood -34mgs % serum creat-inine-1.3mgs %
4.	VC/48	Bilirubin(T)-0.7 mg% Bilirubin(C)-0.3 mg% Protein total-7.0 gm% Albumin-3.9gm% Globulin-3.1gm% SGOT-20u/l, SGPT-25 Alk.P.-138	Total cholesterol-168 mg/dl HDL cholesterol-380 mg/dl VLDL cholesterol-29 mg/dl LDL cholesterol-101 mg/dl Triglycerides-433 mg/dl	Blood urea -26 mg% Serum creatinine -1.0 mg% Serum uric acid-4.9 mg%	Bilirubin(T)-0.72 mg/dl Bilirubin(D)-0.3 mg/dl Protein total -6.2 mg/dl Albumin-3.6 SGOT-20u/l, SGPT-25 Alk.P.-430	Cholesterol-198 mg/dl	NA

5.	F/29	NA	NA	NA	NA	NA	NA
6.	NS/15	Bilirubin(T)-0.5 mg/dl Bilirubin(D)-0.3 mg/dl Protein total- 7.1 g/dl Albumin-3.4 g/dl SGOT-10u/l, SGPT-12 Alk.P.-103	Total cholesterol- 185 mg% HDL cholesterol- 42 mg% VLDL cholesterol- 21 mg% LDL cholesterol- 122 mg% Triglycerides- 105 mg%	Blood sugar -90 mg% Blood urea -19 mg% Serum creatinine -0.8 mg%	NA	NA	NA
7.	PR/48	Bilirubin(T)-1.57 mg/dl Bilirubin(D)-0.14 mg/dl Bilirubin(ID)-1.43 mg/dl Protein total-6.9 mg/dl SGOT-29, SGPT-22 Alk.P.-183.8	NA	Blood-34 mgs/dl urea Serum-1.2mg/dl creatinine Uric-2.8mg/dl acid	Bilirubin(T)- 0.6mg% Bilirubin(D)- 0.6 mg% Bilirubin(ID)- 0.5 mg% Protein total- 6.4 mg% Albumin-3.7 mg% SGOT-49u/l, SGPT-38u/l, GGPT-17u/l Alk.P.-17 u/l	Total choles- trol-198 mg/dl HDL cholesterol -49 mg% LDL cholesterol -150 mg% VLDL cholest- rol-27 mg% Triglycerides -136 mg%	Blood urea- 17mg% Serum creat inine-0.6 mg% Calcium-9.7 mg% Phosphorus- 4.3 mg% Sodium-114 meq/l Chloride- 107 meq/l
8.	MS/28	NA	NA	NA	NA	NA	NA
					Bilirubin(T) -0.5 mg/dl Protein total -6.6 g/dl Albumin-4.2 g/dl SGOT-62 u/l, SGPT-138 u/l Alk.P.-8 u/l	Total chol- estrol-146 mg/dl HDL choles- trol-32 mg/ dl LDL choles- trol-53 mg/ dl Triglycer- ides-306 mg/dl	Blood urea -33 mg/dl Serum creatinine -0.5 mg/dl

9. PS/29

Bilirubin(T)-  
0.4 mg/dl  
Bilirubin(D)-  
-0.2 mg/dl  
Bilirubin(ID)-  
0.2 mg/dl  
Protein total-  
7.6 g/dl  
Albumin-4.4 g/dl  
SGOT-126 u/l,  
SGPT-49 u/l  
GGTP-38 u/l  
Alk.P.-217 u/l

Total cholest-  
rol-205 mg/dl  
HDL cholestrol-  
31.25 mg/dl  
VLDL cholestrol-  
26.99%  
LDL cholestrol-  
118.42 mg/dl  
Triglycerides-  
433 mg/dl

Blood urea  
-45 mg/dl  
Serum creat-  
inine-0.90  
mg/dl  
Calcium-  
10.1 mg/dl  
Phosphorus-  
4.1 mg/dl  
Sodium-147  
mEq/l  
Chloride-  
103 mEq/l  
Potassium-  
4.20 mEq/l

Bilirubin(T)-  
-0.7 mg/dl  
Bilirubin(D)-  
0.2 mg/dl  
Bilirubin(ID)-  
0.5 mg/dl  
Protein total-  
7.7 g/dl  
Albumin-4.6 g/dl  
SGOT-253 u/l,  
SGPT-365 u/l  
GGTP-89 u/l  
Alk.P.-473 u/l

Total cholest-  
rol-156  
mg/dl  
HDL cholest-  
rol-22.15 mg%  
LDL cholest-  
rol-94.09 mg%  
VLDL cholest-  
rol-27.35 mg%  
Trigly-  
cerides-187 mg/dl

Total cholest-  
rol-136.8 mg/dl  
HDL cholest-  
rol-46.2 mg/dl  
LDL cholest-  
rol-56.5 mg/dl  
VLDL cholest-  
rol-34.1 mg/dl

Blood urea  
17 mg/dl  
Serum creati-  
nine-1.0 mg/d  
Calcium-9.7  
mg/dl  
Phosphorus-  
2.9 mg/dl  
Sodium-150 mE  
mEq/l  
Chloride-105  
mEq/l  
Potassium-  
4.90 mEq/l

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10. MN/30

Bilirubin(T)-  
1.7 mg/dl  
Bilirubin(D)-  
1.13 mg/dl  
Bilirubin(ID)-  
0.57 mg/dl  
SGOT-28 u/l,  
SGPT-35 u/l,  
Alk.P.-229 u/l

Total cholest-  
rol-185 mg/dl  
HDL cholest-  
rol-26mg/dl  
VLDL cholest-  
rol-93 mg/dl  
LDL cholest-  
rol 106 mg/dl  
Triglycerides-  
506 mg/dl

Blood urea  
46 mg/dl  
Serum creat-  
inine-1.05 mg/dl  
Calcium-  
8.25 mg/dl

Bilirubin(T)-  
0.7 mg/dl  
Bilirubin(D)-  
0.3 mg/dl  
SGOT-22.8iu/l  
SGPT-27.6iu/l  
Alk.P.-360.5  
iu/l

Total cholestrol-mg/dl  
136.8 mg/dl  
HDL cholest-  
rol-46.2 mg/dl  
LDL cholest-  
rol-56.5 mg/dl  
VLDL cholest-  
rol-34.1 mg/dl

Serum urea-29.3  
Serum creatinine  
-1.0 mg/dl

## I CLAIM:

1. A process on ayurvedic prepration comprising in the steps of subjecting silver, mercury, sulphur and arsenic trisulphide to the steps of detoxification, grinding the detoxified mercury and silver in the presence of a citrus juice and then adding detoxified sulphur and again subjecting to the step of grinding to obtain a greyish black powder, adding detoxified arsenic trisulphide thereto and subjecting to the step of grinding, imparting a shape such as a ball thereto, coating the ball with detoxified sulphur in the presence of a citrus juice and subjecting the coated ball to the step of slow firing, adding detoxified arsenic tripsulphide and firing, repeating said steps of addition and firing ground in a citrus juice such that the weight of the ball is reduced by at least 10% to obtain an intermediate, adding serpentine and delphenium root thereto.

2. A process as claimed in claim 1 wherein the coated balls are introduced into an earthen vessel, sealed and then fired in the presence of cow dung.

3. A process as claimed in claim 1 wherein silver is detoxified by heating silver shets to a red hot state, and then introducing into sesame oil, subjecting the sheets to repeated steps of heating and treatment with sesame oil.

4. A process as claimed in claim 3 wherein the sesame treated silver is subjected to repetitive steps of heating and then treating with butter milk.

5. A process as claimed in claim 4 wherein the butter milk treated silver is subjected to repetitive steps of heating and then treating with cow urine.

6. A process as claimed in claim 5 wherein the cow urine treated silver is then subjected to repetitive steps of heating and treatment in a herbal composition comprising amla, harar and bahera.

7. A process as claimed in claim 1 wherein the herbal treated silver is subjected to repetitive steps of heating and treatment with kulthi.

8. A process as claimed in claim 1 wherein the citrus juice is lemon juice.

9. A process as claimed in claims 3 to 7 wherein said repetitive steps comprise 7 repetitive steps.

10. A process as claimed in claim 1 wherein the step of detoxification of mercury comprises in preparing an amalgam of copper, mercury and a citrus juice, subjecting such an amalgam to repeated steps of distillation to obtain detoxified mercury.

11. A process as claimed in claim 1 wherein the step of detoxification of sulphur comprises in heating crystalline sulphur in the presence of melted butter, and then introducing into triffla to obtain a scum of pure sulphur which is then removed therefrom.

12. A process as claimed in claim 1 wherein the step of detoxification of arsenic trisulphide comprises in wrapping arsenic trisulphide in cotton cloth and then introduced in a vessel of calcium oxide solution and into another vessel of pumpkin juice and boiled each time for a period of 3 to 5 hours.

13. A process as claimed in claim 1 wherein one part of detoxified silver is ground with one part of detoxified mercury in a citrus juice and that one part of detoxified sulphur is then added thereto obtain a greyish black powder.

14. A process as claimed in claim 12 wherein one part of arsenic trisulphide ground in a citrus juice is added to the greyish black powder and made into a shape.

15. A process as claimed in claim 14 wherein one part of detoxified sulphur is ground in citrus juice and coated to said shape and then introduced in said vessel and tired in cowdung.

16. A process as claimed in claim 1 wherein vessel containing said fired mixture is opened and further arsenic trisulphide ground in the presence of lemon juice is added, the vessel closed and again fired and subjected to repeated steps to obtain a potent preparation.

17. A process as claimed in claim 16 wherein one part of the potent preparation is added to one part of serpentine and one part of delphenium root and ground in distilled rose water followed sandal wood water and to latakasturi water.

18. A process for producing an ayurvedic preparation for the treatment of leukemia substantially as herein described.

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(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization  
International Bureau



(43) International Publication Date  
15 March 2001 (15.03.2001)

PCT

(10) International Publication Number  
**WO 01/17540 A1**

- (51) International Patent Classification<sup>7</sup>: **A61K 35/78**, 33/02, 33/36, 33/28, 33/38, A61P 35/02 (74) Agent: **BANERJEE**, Sudipta; L.S. Davar & Co., Monalisa, Flats 1B & 1C, 17 Camac Street, Calcutta 700 017 (IN).
- (21) International Application Number: **PCT/IN99/00042** (81) Designated State (*national*): **US**.
- (22) International Filing Date: 7 September 1999 (07.09.1999) (84) Designated States (*regional*): European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).
- (25) Filing Language: English
- (26) Publication Language: English **Published:**  
— *With international search report.*
- (71) Applicant and  
(72) Inventor: **PRAKASH**, Vaidya, Balendu [IN/IN]; Mandir Marg, Turner Road, Clement Town, Dehradun 248 002 (IN). *For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.*

(54) Title: **A PHARMACEUTICAL AYURVEDIC PREPARATION**

(57) Abstract: The present invention relates to a process on ayurvedic preparation comprising in the steps of subjecting silver, mercury, sulphur and arsenic trisulphide to the steps of detoxification, grinding the detoxified mercury and silver in the presence of a citrus juice and then adding detoxified sulphur and again subjecting to the step of grinding to obtain a greyish black powder, adding detoxified arsenic trisulphide thereto and subjecting to the step of grinding, imparting a shape such as a ball thereto, coating the ball with detoxified sulphur in the presence of a citrus juice and subjecting the coated ball to the step of slow firing, adding detoxified arsenic trisulphide and firing, repeating said steps of addition and firing ground in a citrus juice such that the weight of the ball is reduced by at least 10 % to obtain an intermediate, adding serpentine and delphenium root thereto.

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DECLARATION FOR UNITED STATES PATENT APPLICATION,  
POWER OF ATTORNEY, DESIGNATION OF CORRESPONDENCE ADDRESS

Attorney Docket  
**31446-179039**

As a below named inventor, I hereby declare that my residence, post office address and citizenship are as stated below next to my name, and that I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled A PHARMACEUTICAL AYURVEDIC PREPARATION the specification of which

☐ is attached hereto.

☐ was filed on \_\_\_\_\_, as Provisional Application No. \_\_\_\_\_, and was amended on \_\_\_\_\_ if applicable.

☒ was filed under the Patent Cooperation Treaty on September 7, 1999, Serial No. PCT/IN99/00042, the United States of America being designated.

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose to the Patent and Trademark Office all information known to me to be material to patentability as defined in Title 37, Code of Federal Regulations, §1.56(a).

I hereby claim foreign priority benefits under Title 35, United States Code, §119 of any United States Provisional Application listed below: United States Provisional Application No. \_\_\_\_\_, filed \_\_\_\_\_.

I hereby claim foreign priority benefits under Title 35, United States Code, §119 of any foreign application(s) for patent, utility model, design or inventor's certificate listed below and have also identified below any foreign application(s) for patent, utility model, design or inventor's certificate having a filing date before that of the application(s) on which priority is claimed:

Prior Foreign Application(s)			Priority Claimed	
Number	Country	Date Filed	Yes	No

I hereby appoint the following attorneys and agents to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith: George H. Spencer (Reg. No. 18,038), Robert J. Frank (Reg. No. 19,112), Norman N. Kunitz (Reg. No. 20,586), Gabor J. Kelemen (Reg. No. 21,016), Marina V. Schneller (Reg. No. 26,032), Robert Kinberg (Reg. No. 26,924), Allen Wood (Reg. No. 28,134), Ashley J. Wells (Reg. No. 29,847), James R. Burdett (Reg. No. 31,594), Michael A. Gollin (Reg. No. 31,957), Catherine M. Voorhees (Reg. No. 33,074), Julie Petruzzeli (Reg. No. 40,769), Michael A. Sartori (Reg. No. 41,289), Fei-Fei Chao (Reg. No. 43,538), Charles C.P. Rories (reg. No. 43,381), and Jeffrey W. Gluck (Reg. No. 44,457), all at Suite 1000, 1201 New York Avenue, N.W., Washington, D.C. 20005-3917, Telephone: (202) 962-4800, Telefax: (202) 962-8300.

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The undersigned hereby authorizes the U.S. attorneys named herein to accept and follow instructions from the undersigned's assignee, if any, and/or, if the undersigned is not a resident of the United States, the undersigned's domestic attorney, patent attorney or patent agent, as to any action to be taken in the Patent and Trademark Office regarding this application without direct communication between the U.S. attorneys and the undersigned. In the event of a change in the person(s) from whom instructions may be taken, the U.S. attorneys named herein will be so notified by the undersigned.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under §1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.



DECLARATION FOR UNITED STATES PATENT APPLICATION,  
POWER OF ATTORNEY, DESIGNATION OF CORRESPONDENCE ADDRESS

Attorney Docket  
31446-179039

Title: A PHARMACEUTICAL AYURVEDIC PREPARATION

Signature: \_\_\_\_\_

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204250-0450200T